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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/579,952

05/22/2006

Edward R.B. McCabe

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MORRISON & FOERSTER LLP  
12531 HIGH BLUFF DRIVE  
SUITE 100  
SAN DIEGO, CA 92130-2040

EXAMINER

BOWERS, NATHAN ANDREW

ART UNIT

PAPER NUMBER

1797

MAIL DATE

DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/579,952	<b>Applicant(s)</b> MCCABE ET AL.	
	<b>Examiner</b> NATHAN A. BOWERS	<b>Art Unit</b> 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 13 February 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 5-27 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 5-27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

**DETAILED ACTION**

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

- 1) Claims 5-9, 12-16, 18, 20, 22, 25 and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Livesey (US 4865871).

With respect to claim 5, Livesey discloses a kit comprising a self-contained cell culture vessel that includes a sample holder (Figure 4:100) for accommodating cell reservoirs (Figure 4:111) and media reservoirs (Figure 4:111). This is disclosed in column 17, lines 6-17. Column 15, lines 3-21 state that the sample holder is positioned within a gas reservoir (Figure 4:90) capable of being used to hold a dry nitrogen gas. Column 8, lines 14-45 indicate that cells and a cryoprotectant are disposed in the cell reservoir, and column 8, lines 39-45 specifically indicate that the cyroprotectants are added to a cell culture.

With respect to claim 6, Livesey discloses the kit set forth in claim 5 wherein the kit is maintained at subzero temperatures. Livesey indicates in column 15, lines 33-39 that the kit includes a container (Figure 4:99) for holding cryogenic cooling means.

With respect to claim 7, Livesey discloses the kit set forth in claim 5 wherein a plurality of internal chambers are provided. The cryogenic dewar (99), the gas chamber (90), and each of the individual tissue wells (111) constitute internal chambers.

Art Unit: 1797

With respect to claim 8, Livesey discloses the kit set forth in claim 7 wherein the cryogenic dewar (99) includes a sealable top opening through which the gas reservoir is introduced. The gas reservoir further includes a plurality of seals (Figure 4:97) that regulate the introduction of various gases for drying, treatment and flushing. This is disclosed in 15, lines 8-21. Furthermore, the cell reservoirs and media reservoirs (111) are capable of fluid communication with the internal chamber of the gas reservoir. As previously noted, the vessel as a whole is capable of being sealed (see Figure 2), and is made of a material capable of withstanding subzero temperatures.

With respect to claims 8 and 25, Livesey discloses the kit set forth in claim 8 wherein a liquid impermeable flexible partition (Figure 6:114) is disposed within the internal chamber of the gas reservoir (90). Column 17, lines 6-29 state that the membranes are positioned over the cell and media reservoirs (111) and permit gas transfer to the cell and media reservoirs. Accordingly, a first space is formed within the cell and media reservoirs that are capable of containing a liquid, and a second space is formed within the gas reservoir capable of maintaining dry nitrogen gases used in dehydration processes. Livesey teaches that the edges of the membrane are sealed to each reservoir side wall (Figure 6:115) using special vacuum adhesives.

With respect to claim 12, Livesey discloses the kit set forth in claim 7 wherein the gas reservoir (90) is a self-contained capsule disposed within the internal chamber of the cryogenic dewar (90).

Art Unit: 1797

With respect to claims 13-15 and 14, Livesey discloses the kit set forth in claim 7 wherein the gas reservoir (90) is disposed outside of and surrounds the internal chambers established by the cell and media reservoirs (111).

With respect to claim 16, Livesey discloses the kit set forth in claim 8 wherein the sealable top opening of the cryogenic dewar is a mechanically operated valve. Mechanically operated valves (97) are additionally used to introduce fluids to the gas reservoir.

With respect to claims 18, 20, 22 and 26, Livesey discloses the kit set forth in claim 8 wherein a temperature measuring device is used to monitor and control the temperature within the system. The kit includes a plurality of chambers and channels that serve to connect the measuring device to each of the multiple components of the system.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

Art Unit: 1797

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

2) Claims 5-10, 13, 15-18, 20, 22 and 25-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rajotte (US 5863715) in view of Wilson (US 5693537).

With respect to claims 5 and 7, Rajotte discloses a kit comprising a self-contained cell culture vessel comprising a cell reservoir and a media reservoir in the form of an internal chamber (Figure 6:4). Rajotte teaches in column 4, lines 20-60 that cells, DMSO cryoprotectant, and cell culture media are retained within the internal chamber. Rajotte, however, does not indicate that a gas reservoir is provided.

Wilson discloses a tissue flask for cell culture that comprises a culture chamber (Figure 5:40) bounded on one side by a gas permeable membrane (Figure 5:120) in communication with a gas reservoir (Figure 5:190). Column 7, lines 47-67 indicate that

Art Unit: 1797

critical gases are moved to and from the culture chamber through the gas permeable membrane.

Rajotte and Wilson are analogous art because they are from the same field of endeavor regarding cell culture systems.

At the time of the invention, it would have been obvious to provide the Rajotte kit with an additional storage unit at the upper portion capable of serving as a gas reservoir. Prior to and following freezing, this additional reservoir would provide the cell culture with necessary critical gases required for growth and maintenance. Wilson teaches that the coupling of a gas reservoir to a cell culture compartment using a gas permeable membrane is well known in the art. Gas permeable membranes such as the one described in Wilson are formed from materials well known in the art, and could be incorporated into the Rajotte kit with only minor structural alteration.

With respect to claim 6, Rajotte and Wilson disclose the apparatus set forth in claim 5. In addition, Rajotte indicates that the kit is intended for use at subzero temperatures as a cryopreservation bag.

With respect to claim 8, Rajotte and Wilson disclose the apparatus set forth in claim 7. Rajotte additionally states that the internal chamber (4) is used to accommodate a cell culture solution and a cryoprotectant. Rajotte further indicates that internal chamber is also in communication with auxiliary compartments (3a) through an opening that can be heat sealed upon removal of an auxiliary compartment.

Art Unit: 1797

As previously noted, Wilson discloses the use of a gas reservoir sealed using a gas permeable membrane. Wilson further states that the gas reservoir is sealed at a gas access opening (Figure 3:140).

With respect to claims 9 and 10, Rajotte and Wilson disclose the apparatus set forth in claim 7. As previously described, Wilson describes the use of a flexible partition for separating a first liquid space from a second space capable of containing a gas. Wilson teaches that the edges of the partition are sealed to prevent liquid communication between each side of the partition. Wilson further teaches that the membrane is a polymeric material naturally expandable in character, and that the other surrounding portions of the gas reservoir are formed from a rigid material.

With respect to claims 13 and 15, Rajotte and Wilson disclose the apparatus set forth in claim 7. Rajotte describes the use of self-contained capsules sealably connected to an internal chamber.

With respect to claims 16, 17 and 25, Rajotte and Wilson disclose the apparatus set forth in claim 8. Rajotte teaches that the auxiliary compartments (3a) are sealed to the internal chamber (4) using heat seals that are temperature sensitive and work to restrict access upon the application of heat. Additionally, safety seals are considered to be well known in the art.



With respect to claims 18, 20, 22, 26 and 27, Rajotte and Wilson disclose the apparatus set forth in claim 8. Rajotte additionally teaches that thermocouples are distributed within the kit in order to detect temperature throughout each reservoir. The reservoir is in turn connected to inlet and outlet ports and channels. This is described in column 3, lines 3-15. Likewise, Wilson teaches that it is critical in cell culture systems to regulate pH and critical gas levels in order to optimize growth. The use of sensors is required to effectively monitor pH, oxygen and carbon dioxide.

3) Claims 11 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rajotte (US 5863715) in view of Wilson (US 5693537) as applied to claims 8 and 18, and further in view of Mullen (US 5679565).

Rajotte and Wilson disclose the apparatus set forth in claims 8 and 18 as set forth in the 35 U.S.C. 103 rejections above. As previously noted, inlet and outlet ports are provided for adding and removing additional material through a fluid channel to the internal chamber and cell and/or media reservoirs. This is disclosed by Rajotte in column 4, lines 20-60. Figure 6 indicates that the fluid channels comprise septa that serve as valves to regulate flow. Furthermore, essentially any number of additional detachable pouches in the form of absorbent chambers could be added to the top portion of the Rajotte device. Rajotte, however, does not expressly indicate that a cell filter is provided.

Mullen discloses a means for storing and preserving tissues that includes an internal compartment (Figure 1:12) serviced by a channel (Figure 1:28) for conveying

Art Unit: 1797

fluids. Mullen teaches in column 5, lines 7-22 that a cell filter (Figure 1:22) is attached to the channel.

Rajotte and Mullen are analogous art because they are from the same field of endeavor regarding tissue preservation means.

At the time of the invention, it would have been obvious to provide the kit of Rajotte with a filter means at the inlet/outlet channel capable of retaining tissue cells within the kit while preventing the passage of contaminants. Filter means, as evidenced by Mullen, are considered to be well known in the cell culture art, and are beneficial because they serve to prevent contamination. The cell filter of Mullen would serve the additional advantage if incorporated into the Rajotte kit of maintaining stored tissue inside the reservoir, thereby preventing undesirable tissue loss during the removal of fluids.

4) Claims 19, 21 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rajotte (US 5863715) in view of Wilson (US 5693537) as applied to claims 18 and 20, and further in view of Anderson (US 20060246490).

Rajotte and Wilson disclose the kit set forth in claims 18 and 20 as set forth in the 35 U.S.C. 103 rejections above, however do not expressly state that the measuring device includes a MEMS. Furthermore, Rajotte and Wilson do not teach the use of ball valves for regulating fluid movement.

Anderson discloses a substrate for measuring the presence of biochemical analytes in a sample solution. Anderson teaches in paragraph [0183] that ball valves

Art Unit: 1797

are common means for controlling fluid motion in a channel. Anderson additionally teaches in paragraphs [0338] and [0339] that micro electro mechanical systems are likewise commonly used as valve means.

Rajotte and Anderson are analogous art because they are from the same field of endeavor regarding biochemical analysis devices.

At the time of the invention, it would have been obvious to provide any known means for regulating fluid flow in the Rajotte device as a substitute for the mechanisms already disclosed by Rajotte. Anderson teaches that MEMS and ball valve structures are commonly implemented in microfluidic systems, and that each represents a functionally equivalent way to restrict fluid flow. Accordingly, it would have been obvious to implement these well known features in the Rajotte kit in order to predictably and effectively control the movement of fluid to and from the various reservoirs.

### ***Response to Arguments***

Applicant's arguments filed 13 February 2009 with respect to the 35 U.S.C. 102 rejections under Livesey have been fully considered but they are not persuasive.

*Applicant's principle arguments are*

*(a) Livesey does not describe a self-contained apparatus for culturing cells, but instead only describes an apparatus for cryopreserving cells. Livesey does not disclose a media reservoir because Livesey never teaches that the tissue reservoir can contain a liquid cell culture medium.*

In response, please consider the following remarks.

Art Unit: 1797

It is agreed that the Livesey apparatus is used to cryoprepate a biological tissue for storage and subsequent transplantation. However, prior to vitrification and freezing, a tissue sample is mixed with a cryoprotectant for over a period of hours. This is disclosed in column 8, lines 14-24. Column 8, lines 39-45 specifically states that the cryoprotectants are applied to a tissue sample in the form of a *cell culture*. Accordingly, it is understood that reservoirs (Figure 4:111) function as cell reservoirs and media reservoirs because they accommodate both cells and culture fluids.

It is further noted that the claims do not require cell growth, but rather only conditions suitable for cell growth. Prior to vitrification/supercooling, the culture sample is suitable for cell growth.

Applicant's arguments filed 13 February 2009 with respect to the 35 U.S.C. 103 rejections under Rajotte and Wilson have been fully considered but they are not persuasive.

*Applicant's principle arguments are*

*(a) The side compartments of Rajotte are not media reservoirs because they are not used to dilute the cryoprotectant to a volume suitable for cell growth. Instead, the side compartments are used as auxiliary units and treated to remove the cryoprotectant.*

In response, please consider the following remarks.

The internal chamber (Figure 6:4) of Rajotte is used as a media reservoir and a cell reservoir. Columns 3 and 4 indicate that a cryoprotectant, tissue samples, and a tissue culture medium are all added to the internal chamber for later processing.

The claims do not require that the cell reservoir, media reservoir, and internal chamber are constructed as separate and independent chambers. In fact, Applicant indicates in Figure 1 of the drawings submitted 5/22/2006 that only a single chamber is used as a cell reservoir, media reservoir, and internal chamber.

*(b) Wilson does not disclose a device designed for carrying out cryopreservation, and Wilson's basal medium compartment does not combine with cells and cryoprotectant in the cell culture compartment to dilute the cryoprotectant.*

In response, please consider the following remarks.

The Wilson reference is not relied on for teaching regarding the combination of a cryoprotectant with a cell culture medium. Rajotte already discloses this limitation. Wilson is merely relied on for teachings regarding the use of a gas reservoir in communication with a cell reservoir.

Upon review of Wilson, one of ordinary skill in the art would have found it obvious to provide the Rajotte kit with an additional storage unit at the upper portion capable of serving as a gas reservoir. Prior to and following freezing, this additional reservoir would provide the cell culture with necessary critical gases required for growth and maintenance. Wilson teaches that the coupling of a gas reservoir to a cell culture compartment using a gas permeable membrane is well known in the art. Gas permeable membranes such as the one described in Wilson are formed from materials well known in the art, and could be incorporated into the Rajotte kit with only minor structural alteration.

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NATHAN A. BOWERS whose telephone number is (571)272-8613. The examiner can normally be reached on Monday-Friday 7 AM to 4 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1797

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/William H. Beisner/  
Primary Examiner, Art Unit 1797

/Nathan A Bowers/  
Examiner, Art Unit 1797